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Public Health Agency of Canada (PHAC)

Canada Communicable Disease Report CCDR

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PREVENTING PNEUMOCOCCAL DISEASE: A CANADIAN CONSENSUS CONFERENCE* - 16-18 February 1998

Introduction

Streptococcus pneumoniae is an important cause of illness, hospitalization, and death worldwide. It is responsible for meningitis, pneumonia, otitis media, sinusitis, and bacteremia in adults and children. Among all adult community-acquired pneumonias requiring hospital admission, *S. pneumoniae* ranks first among known microbial causes and accounts for approximately 30% to 50% of such cases[1]. It is estimated that in non-industrialized countries pneumococcal pneumonia results in the death of over 1 million children each year, half of whom are < 1 year of age[2]. In industrialized countries, invasive disease due to *S. pneumoniae* is a serious problem among the elderly, infants, and those with chronic underlying medical conditions or immune systems that are compromised, either because of disease or immunosuppressive drug therapy.

In the United States, pneumococcal disease is estimated to account for 3,000 cases of meningitis, 50,000 cases of bacteremia, 500,000 cases of pneumonia, and 7,000,000 cases of otitis media each year[3]. The incidence of invasive pneumococcal disease has not been well defined in Canada until relatively recently. Population-based surveillance for invasive pneumococcal disease in metropolitan Toronto-Peel region (population 3.4 million), revealed an overall incidence of 14.4 cases per 100,000 population in 1995, 16.1 cases per 100,000 population in 1996, and 11.8 cases per 100,000 population in 1997[4]. Ninety-two percent of cases were caused by serotypes contained in the current 23-valent pneumococcal vaccine, and 76% of cases belonged to one or more of the high-risk groups defined by the National Advisory Committee on Immunization (NACI)[4]. The Sentinel Health Unit Surveillance System (SHUSS), an active population-based surveillance for laboratory-confirmed disease conducted in nine health units within eight Canadian provinces in 1996, revealed an overall incidence of 15.1 cases of invasive pneumococcal disease per 100,000 population [5]. The age-specific incidence was greatest in children < 5 years of age (55.3 cases per 100,000) and in persons >= 65 years of age (46.4 cases per 100,000). Ninety-four percent of cases were caused by serotypes contained in the 23-valent pneumococcal vaccine[5].

Historically, *S. pneumoniae* was uniformly susceptible to penicillin. The first isolate resistant to penicillin was reported from Australia in 1967[6]. The incidence of penicillin resistance in many areas of the world has been steadily increasing during the past two decades, but has grown at a much higher rate in the past 5 years[7]. The National Centre for *Streptococcus* (NCS) in Edmonton, a voluntary passive reporting system, found that 7.8% of isolates submitted between 1992 and 1995 had diminished susceptibility to penicillin[8]. During 1996 to 1997, this proportion had increased to 10.2%[9]. SHUSS identified 7.4% of isolates having diminished susceptibility to penicillin in 1996[5]. Vancomycin is one of the few antimicrobials to which reduced susceptibility has not been shown. The increase in antibiotic resistant *S. pneumoniae*

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underscores the need for prevention.

A 23-valent polysaccharide pneumococcal vaccine has been available since the 1980s. NACI recommends vaccination for specified groups at high risk of pneumococcal disease; however, vaccine programs and policies for who receives publically funded vaccines are the responsibility of each of the provinces and territories[10]. Only recently have public-health programs in some provinces and territories begun to promote the vaccine's use.

The need for national consensus regarding the control of pneumococcal disease has been recognized. To identify initiatives currently under way in Canada, including publicly funded immunization programs, surveillance, epidemiologic research, and laboratory activities, and to identify priority areas for the future, the Laboratory Centre for Disease Control (LCDC), Health Canada, organized a meeting of national and international stakeholders. The meeting, entitled "Preventing Pneumococcal Disease: A Canadian Consensus Conference" was held in Ottawa, Ontario, 16-18 February 1998. The objectives were to achieve national consensus on the following issues:

surveillance of pneumococcal disease

immunization and publicly funded campaigns

epidemiologic research

antimicrobial resistant *S. pneumoniae*

laboratory activities as they relate to *S. pneumoniae*

The emphasis of the conference was to generate national recommendations on the use of pneumococcal vaccine.

The conference began with a series of presentations by national and international authorities in the area of pneumococcal disease. Participants were then divided into working groups. Each group was asked to consider specific questions when developing their recommendations. The proposed recommendations from each group were then presented to and discussed by the plenary. A consensus process was used to arrive at the final recommendations, in which consensus was broadly defined as that which a majority of participants strongly supported, with acceptance by the rest.

This report presents the final consensus recommendations from each working group. Recommendations are broken down into four categories: 1) surveillance and targeted research; 2) immunization: role in disease prevention; 3) immunization programs: delivery and promotion strategies; and 4) program evaluation and monitoring.

RECOMMENDATIONS

1. Surveillance and targeted research

Invasive pneumococcal disease is not a reportable condition in every province or territory of Canada. However, recent Canadian studies and surveillance activities have better quantified the burden of disease attributable to invasive pneumococcal infections and have identified increasing trends in resistance to penicillin[4,5,8,9]. While there is some Canadian information regarding penicillin resistance, systematic collection of this data in many areas of Canada is not

occurring, as drug-resistant *S. pneumoniae* is not a reportable condition. This information is needed to provide clinicians with data on local drug resistance patterns to guide empiric therapy of serious pneumococcal infections.

The incidence of drug-resistant infections can change rapidly. In some areas of the United States, as many as 30% of pneumococcal isolates are resistant to penicillin[11,12]. Laboratory-based surveillance for invasive pneumococcal disease is critical for monitoring both antibiotic resistance and the serotypes causing disease. With increased use of the 23-valent polysaccharide vaccine, it will also be important to monitor *S. pneumoniae* incidence and the groups at risk of disease to observe changes over time.

Recommendation 1

A national system of surveillance should be established for invasive pneumococcal disease. The surveillance system should include monitoring of serotypes and antimicrobial resistance. All pneumococcal surveillance systems should periodically compare and share information to eliminate gaps in surveillance and obtain the widest possible perspective on invasive pneumococcal disease.

Recommendation 2

Invasive pneumococcal disease should be made nationally notifiable and reportable within all provinces and territories, with minimal core data for all reported cases. Isolates from blood, and cerebrospinal, articular, peritoneal or pleural fluid should be included, but not those from sputum or broncho-alveolar fluid. Common definitions should be used for disease reporting.

Recommendation 3

The collection of a representative sample of isolates in each province and territory or region should be coordinated by a steering committee of epidemiologists and microbiologists, who would receive monthly information from all laboratories in the province on the number of invasive *S. pneumoniae* cases detected from normally sterile sites and the number of these resistant to penicillin, as determined by the oxacillin screen. In addition, a network of laboratories chosen by the steering committee as representative of the provincial or territorial population should send all isolates from normally sterile sites to the provincial laboratory each month.

Recommendation 4

More detailed information, including risk factor and immunization information, should be collected, and the serotype and antibiotic susceptibility determined for a representative sample of reported cases to monitor the impact of immunization on the epidemiology of pneumococcal disease. These pneumococcal isolates may be sent by the provincial laboratory to the NCS for serotyping and confirmation of antibiotic resistance as required.

Recommendation 5

Information regarding the number of cases of invasive pneumococcal disease and the number with resistance to penicillin and other appropriate antibiotics should be forwarded from provincial public-health laboratories to provincial and territorial epidemiologists and LCDC on a monthly basis.

Recommendation 6

Information collected by the surveillance system should be made available at least annually and no later than 6 months after the end of the year, to all those who contribute to its collection and to those who will use it to determine vaccine policy, including NACI and the Advisory Committee on Epidemiology (ACE).

Recommendation 7

SHUSS should periodically monitor invasive pneumococcal isolates to establish disease incidence, populations at risk, and the effect of vaccine introduction. These results should be communicated to NACI, LCDC, ACE, Chief Medical Officers of Health, and the Technical Advisory Committee on Public Health Laboratory Directors in a timely manner. SHUSS may also examine vaccine failures to establish etiology.

Recommendation 8

The Canadian Immunization Monitoring Program, Active (IMPACT) system should be considered as an additional surveillance system in preparation for the introduction of conjugate vaccines in children. Until that time, the systems already mentioned should analyze their data for the burden of disease in children.

Recommendation 9

The following issues should be given high priority in the area of research:

- the potential benefits of periodic revaccination with polysaccharide vaccine and the potential for alternative strategies for long-term protection, including the use of conjugate vaccine
- the efficacy of conjugate vaccines in infants, children, and adults
- vaccine efficacy in certain high-risk groups, including people infected with HIV and those with diabetes
- the incidence of pneumococcal disease and the prevalence of risk factors for people living in special environments and social settings (including Aboriginal populations)
- monitoring the effectiveness of pneumococcal vaccine, after the introduction of immunization programs, by linking clinical outcomes, serotypes, and vaccination status
- development of valid indicators of pneumococcal morbidity and mortality
- updating the meta-analysis on the effectiveness of immunization delivery strategies.

2. Immunization: role in disease prevention

Studies on the burden of illness attributable to pneumococcal disease in Canada yield results that are similar to studies in other countries[4,5,13,14]. For this reason, estimates of pneumococcal vaccine effectiveness and cost-effectiveness from other studies may be extrapolated to the Canadian population. In observational studies, the effectiveness of pneumococcal vaccine in preventing invasive pneumococcal disease has generally ranged from 55% to 80%[13,15,16]. A meta-analysis of nine randomized controlled trials of pneumococcal vaccine concluded that pneumococcal vaccine is efficacious in reducing the frequency of bacteremic pneumococcal pneumonia among adults in low-risk groups[17].

Pneumococcal vaccination has been found to be safe and cost-effective in preventing invasive disease among elderly people and people with certain chronic medical conditions. In terms of cost per life year gained, it compares

favourably with other well accepted preventive and therapeutic interventions, such as influenza immunization, mammography screening, and hypertension screening[18]. A recent economic analysis of the cost-effectiveness of pneumococcal vaccination against bacteremic disease among elderly people in the United States found that pneumococcal vaccination was cost saving in persons >= 65 years of age. Vaccination saved US$8.27 and gained 1.21 quality-adjusted days of life per person vaccinated[19]. A cost-utility analysis in Quebec found that pneumococcal immunization compared favourably with other programs and services provided to seniors or persons with chronic conditions[20]. Other studies have also indicated that pneumococcal vaccination is cost effective[21].

The demonstration of effectiveness and cost-effectiveness are only two of a number of factors involved in the decision to implement a publicly funded immunization program. Other important factors include burden of illness, vaccine safety, antibiotic resistance, political climate, competing health priorities, public demand, media interest, and provider interest. The importance of each of these variables in the decision making process will differ from one province or territory to another.

Recommendations for the use of pneumococcal vaccine are published in the ***Canadian Immunization Guide***[10]. However, the incidence of pneumococcal disease in different populations which may be at greater risk of disease because of biologic or socio- economic factors (e.g. Aboriginal populations, homeless people, people living in correctional facilities, people with solid tumours) is not always known. The ***Canadian Immunization Guide*** is revised by NACI every 4 years to reflect recent evidence regarding groups at increased risk of disease.

Vaccination may not confer lifelong protection against disease. Strategies that may be considered for the future include revaccination or the use of other vaccines, such as the conjugate vaccines currently under development.

Recommendation 10

The evidence strongly supports the inclusion of pneumococcal vaccine in publicly funded immunization programs in all Canadian provinces and territories. The initial priority of pneumococcal immunization programs should be to offer a single dose of vaccine to all high-risk groups, as defined by NACI.

Recommendation 11

NACI should develop a statement on adult immunization, with particular reference to high-risk groups and Aboriginal peoples. Pneumococcal immunization should be included in this statement.

Recommendation 12

NACI should communicate with the Canadian Task Force on Periodic Health Examination to develop consistent pneumococcal immunization recommendations.

Recommendation 13

LCDC and vaccine manufacturers should disseminate current data to each province and territory on the benefit of pneumococcal vaccine in preventing disease, rather than attempting to demonstrate, for example, its benefit in

preventing pneumonia where *S. pneumoniae* has not been isolated from a normally sterile body fluid.

3. Immunization programs: delivery and promotion strategies

The barriers to pneumococcal immunization in Canada include:
1) lack of awareness by health care workers, the public, and policy makers regarding the burden of the disease, the efficacy and cost-effectiveness of pneumococcal immunization, and appropriate adult immunization practices in general; 2) the cost of immunization programs to public-health services and, in some cases, the lack of incentive for physicians to provide immunization; and 3) the lack of infrastructure for recording immunization and identifying high-risk populations. Immunization registries were the subject of a separate consensus conference meeting in March 1998[22]. Recommendations developed from that meeting are pertinent to pneumococcal immunization.

Studies carried out in the province of Quebec indicate that privately funded immunization programs achieve a low immunization rate[23]. As well, evidence on strategies to deliver vaccine indicates that system strategies as opposed to provider or client-oriented strategies are the most effective. Immunization of residents of long-term care facilities can be an effective place to begin, as it is relatively easy in these facilities to ensure complete vaccine coverage. Promotion and implementation of pneumococcal immunization programs can also be facilitated if they are linked with influenza immunization programs which have similar target groups.

Recommendation 14

The following goal and objectives for the control of pneumococcal disease should be adopted throughout the country.

Goal

To reduce illness and death due to pneumococcal disease.

Objectives

To achieve a 40% reduction in the incidence of invasive pneumococcal disease in vaccine-eligible groups by the year 2005. To achieve a 40% reduction in the rate of death due to invasive pneumococcal disease in vaccine-eligible groups by the year 2005.

Recommendation 15

The following goal and objectives for publicly funded immunization programs should be adopted throughout the country.

Goal

To immunize all persons for whom pneumococcal vaccine is recommended by NACI.

Objectives

To initiate a publicly funded pneumococcal immunization program for all persons for whom vaccine is recommended by NACI by the year 2000, in all provinces and territories.

To encourage provinces and territories to develop an implementation strategy to provide vaccine to all persons for whom the vaccine is recommended by NACI by the year 2000.

To achieve and maintain 95% vaccine coverage for residents of long-term care facilities by the year 2003.

To achieve and maintain 80% vaccine coverage in all other groups for whom vaccine is recommended by the year 2003.

To review progress towards achievement of vaccine coverage targets in the year 2002.

To ensure that all recipients of influenza vaccine are also appropriately immunized with pneumococcal vaccine, if eligible.

Recommendation 16

Each province and territory should purchase vaccine for all its population at high risk for pneumococcal disease, including Aboriginal peoples and status members of First Nations.

Strategies for delivery of pneumococcal vaccine

Recommendation 17

Concurrent promotion and administration of pneumococcal and influenza vaccine should be done when appropriate. Both vaccination programs should be promoted in the fall, making use of the media (e.g. television, radio, press releases, posters, and community newspapers).

Recommendation 18

A standard immunization record-keeping form should be used by all health-care providers. Immunization record-keeping systems should be improved at all levels in all provinces and territories to improve access to records for providers and to encourage the public to keep a record of immunization status.

Recommendation 19

Standing orders and/or medical directives should be implemented for pneumococcal vaccination of residents on admission to long-term care facilities, and for vaccination of persons in high-risk groups on discharge from hospitals.

Recommendation 20

Pneumococcal vaccine should be delivered to people in high-risk groups in adult day care, community centres, specialty and non-specialty outpatient clinics for adults and children, as well as hospital emergency departments.

Recommendation 21

Sufficient financial resources should be allocated to public-health organizations and physicians for all aspects of vaccine delivery. When necessary, public-health managers should prioritize nursing tasks on the basis of evidence-based

practice in order to reallocate work for the accomplishment of immunization initiatives.

Strategies for promoting immunization programs

Recommendation 22

LCDC should act as a clearing house for information on the implementation of pneumococcal immunization programs and program evaluation, and should provide each province and territory with a critique of current literature on the cost-effectiveness of pneumococcal vaccination in order to assist decision makers in their determinations about the initiation of vaccination programs.

Recommendation 23

Information about adult immunization, including pneumococcal immunization, should be included in postgraduate training programs (Royal College of Physicians and Surgeons of Canada, Canadian College of Family Physicians), and in medical and nursing school curricula.

Recommendation 24

Information about pneumococcal immunization, pneumococcal disease, antibiotic resistance, and immunization record keeping should be incorporated into continuing medical education activities such as conferences, lectures, and grand rounds.

Recommendation 25

Adult immunization guidelines should be incorporated into practice guidelines at the provincial, territorial, and federal levels.

Recommendation 26

Physicians should receive information (on a provincial and territorial basis) about Vaccine Associated Adverse Event (VAAE) surveillance system reports and be supplied with reporting forms. Timely feedback about adverse events should be provided to health-care providers from national, provincial, and territorial levels.

Recommendation 27

Periodic feedback should be given to the public about vaccine coverage, the impact of immunization programs on pneumococcal disease, and adverse events associated with immunization.

Recommendation 28

Partnerships should be formed to promote pneumococcal immunization at federal, provincial, territorial, and local levels with professional organizations (e.g. Canadian Medical Association, Canadian Paediatric Society, Canadian College of Family Physicians, Canadian Nurses Association, Canadian Association of Paediatric Hospitals, Canadian Infectious Disease Society) and non-governmental organizations (e.g. Canadian Public Health Association, Rotary Club, Lung Association, Diabetes Association, Heart and Stroke Foundation, Cancer Society).

Recommendation 29

Promotional strategies should be developed at the local level using social marketing approaches, in order to reach different social groups (e.g. targeting banks, churches, bingo halls, bus stops, pharmacies, post offices, etc.).

Recommendation 30

A competitive national market place for vaccine purchase should be promoted.

4. Program evaluation and monitoring

Evaluation of pneumococcal immunization programs will be critical to ensure that the objectives of the program have been met, including, vaccine coverage, impact on disease burden, occurrence of adverse events, effectiveness of program delivery strategies, and awareness of and acceptance by health-care providers and the public. The availability of measurable objectives for the control of pneumococcal disease and for pneumococcal immunization programs will facilitate evaluation. Given the difficulties in determining rates of pneumococcal disease where *S. pneumoniae* is not isolated from a normally sterile body fluid, it will be useful to limit the scope to documented invasive disease; however, it is anticipated that immunization programs will prevent more than just these documented invasive infections.

Strategies to evaluate immunization programs

Recommendation 31

The effectiveness of program delivery strategies should be evaluated at all levels (national, provincial, territorial, and local) using recognized methodologies.

Recommendation 32

Since both private and public delivery systems exist across Canada, each province and territory should evaluate how well national coverage goals are being achieved and modify its delivery system when needed.

Recommendation 33

Crude estimates of vaccine coverage should be obtained using common methodology across Canada (i.e. doses distributed minus doses wasted as the numerator; adjusted census data for those aged >= 65 years and high-risk groups aged 2 to 64 years as the denominator). In addition, LCDC, in conjunction with the provinces and territories, should conduct periodic vaccine coverage surveys, including vaccine coverage in long-term care facilities. A common methodology, including common definitions for numerator and denominator data, should be used for calculating vaccine coverage levels. Methods of improving vaccine coverage should be suggested.

Recommendation 34

Mortality data should be collected as a crude measure of disease impact.

Recommendation 35

The national VAAE surveillance system should continue to collect information

not meeting full LCDC reporting criteria for severity (under the "other severe or unusual events" section). The provinces and territories should maintain the review of the reports as a centralized function.

Recommendation 36

Health-care providers' acceptance of pneumococcal immunization programs should be assessed through knowledge, attitudes, and practice surveys.

Recommendation 37

The general population should be surveyed to assess the effectiveness of promotional materials about pneumococcal immunization programs.

Glossary

Cost-effectiveness study: This form of economic analysis seeks to determine the costs and effectiveness of an activity or to compare similar alternative activities to determine the relative degree to which they will obtain the desired objectives or outcomes. The preferred action or alternative is one that requires the least cost to produce a given level of effectiveness, or provides the greatest effectiveness for a given level of cost. In the health-care field, outcomes are measured in terms of health status[24].

Cost-benefit study: An economic analysis in which the costs of medical care and the benefits of reduced loss of net earnings due to preventing premature death or disability are considered. The general rule for allocation of funds in a cost benefit analysis is that the ratio of marginal benefit (the benefit of preventing an additional case) to marginal cost (the cost of preventing an additional case) should be >= 1[24].

Cost-saving: An intervention that is found to reduce medical expenses and improve health in an economic analysis.

Cost-utility: A form of economic evaluation in which the outcomes of alternative procedures or programs are expressed in terms of a single "utility-based" unit of measurement. A widely used measurement is the quality-adjusted life year[24].

Effectiveness: A measure of the extent to which a specific intervention, procedure, regimen, or service, when deployed in the field in routine circumstances, does what it is intended to do for a specified population[24].

Efficacy: The extent to which a specific intervention, procedure, regimen, or service produces a beneficial result under ideal conditions. Ideally, the determination of efficacy is based on the results of a randomized controlled trial [24].

High-risk groups for pneumococcal disease, as defined by NACI: Persons >= 65 years of age, and persons > 2 years of age with asplenia, splenic dysfunction or sickle-cell disease, chronic cardiorespiratory disease (except asthma), cirrhosis, alcoholism, chronic renal disease, nephrotic syndrome, diabetes mellitus, chronic cerebrospinal fluid leak, HIV infection, and other conditions associated with immunosuppression (Hodgkin's disease, lymphoma, multiple myeloma, induced immunosuppression for organ transplantation)[10].

Invasive pneumococcal disease: Pneumococcal infections identified by isolation of. *S. pneumoniae* from normally sterile body fluid (i.e. blood, and cerebrospinal, pleural, peritoneal, or articular fluid).

Quality-adjusted life year: An adjustment of life expectancy that reduces the overall life expectancy by amounts which reflect the existence of chronic conditions causing impairments, disability, and/or handicap as assessed from health survey data, hospital discharge data, etc. In practice, numerical weights representing severity of residual disability are established by the judgment of patients and health professionals[24].

Reduced susceptibility to penicillin: *S. pneumoniae* isolates identified using National Committee for Clinical Laboratory Standards methods and breakpoints, as having either high-level resistance (minimum inhibitory concentration [MIC] >= 2µg/mL) or intermediate susceptibility (MIC 0.1µg/mL to 1.0µg/mL) to penicillin or isolates identified using oxacillin screening as being nonsusceptible to penicillin (i.e. zone size <= 19 mm)[25].

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RESPIRATORY VIRUS SURVEILLANCE

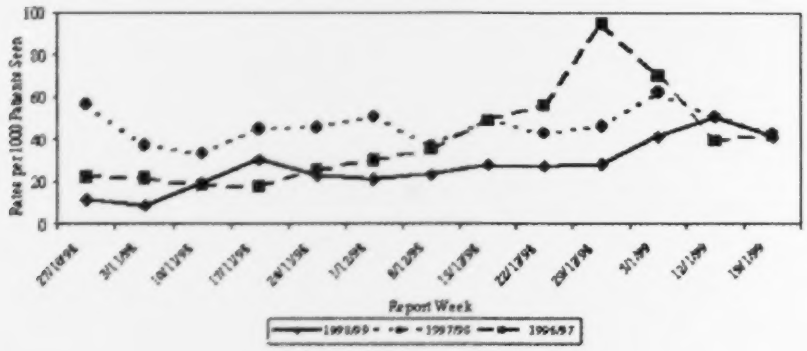
FluWatch Project

FluWatch, Canada's national influenza surveillance program, began its third season on 14 October 1998. The program collects, synthesizes, and prepares reports using data from four main sources: 1) provincial and territorial assessments of influenza activity based on indicators which include reports from physicians and health units, and sickness-absence data; 2) sentinel physician reporting of influenza-like illness (ILI); 3) laboratory reports of positive influenza tests; 4) the World Health Organization, the United States Centers for Disease Control and Prevention, and other international reports of influenza activity.

Currently, FluWatch has 165 sentinel physicians participating in the program. ILI is defined as, "acute febrile (fever and or chills) respiratory illness characterized by one or more of the following: cough, sore throat, arthralgia, myalgia or prostration which, in the opinion of the attending physician, could be due to influenza virus." This article provides a brief summary of influenza activity up to 19 January 1999.

The weekly rates of ILI reported to FluWatch (Figure 1) during the current season have shown a small upward trend since the end of December 1998; however, the rates are lower than those reported to FluWatch during the same period for the previous two seasons. Since September 1998, the FluWatch program has received reports on 15,138 laboratory tests for respiratory viruses; 368 are confirmed as influenza type A and six as type B. The provincial distribution of the influenza A virus specimens is as follows: New Brunswick (1), Quebec (13), Ontario (92), Manitoba (99), Saskatchewan (21), Alberta (104), and British Columbia (38). The distribution of the influenza B specimens is as follows: Ontario (5) and Quebec (1).

Figure 1. Influenza-like illness, weekly reporting rates, Canada, 1998-1999, 1997-1998, and 1996-1997



FluWatch program reports can be accessed through the FluWatch Website <http://www.phac-aspc.gc.ca/fluwatch/index.html>. Information can also be obtained from the ***Infectious Diseases News Brief*** Website <http://www.phac-aspc.gc.ca/bid-bmi/dsd-dsm/nb-ab/index.html. World Health Organization influenza reports can be accessed through the FluNet Website <http://rhone.b3e.jussieu.fr/flunet/www/>.

Source:

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